510(K) Summary K132104

Synvasive Technology, Inc.
8690 Technology Way
Reno, NV 89521
Phone: 916-939-3913
Contact: Michael G. Fisher, President
Date prepared: September 4, 2013

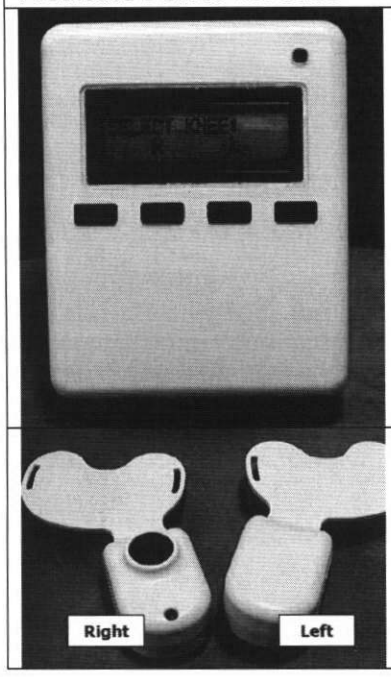
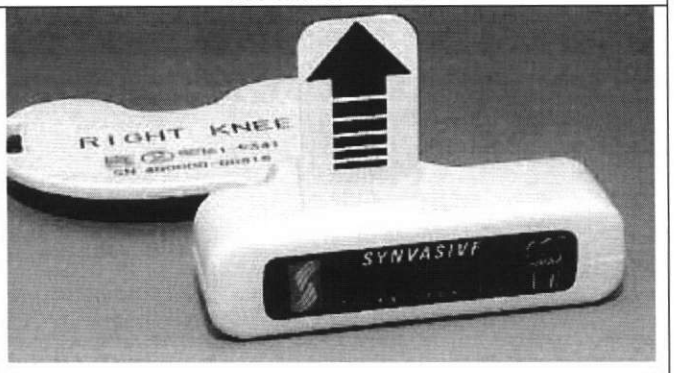
1. Trade Name: eLibra® Soft Tissue Force Sensor
   Common Name: Intraoperative orthopedic joint assessment aid
   Classification Name: Stereotaxic instrument., product code ONN,
   Regulation: 882.4560 Class of device: Class 2.
   Type of submission: Device Modification, Special 510(k).

2. The legally marketed device to which we are claiming equivalence [807.92(a)(3)] : K070108 eLibra Dynamic Knee Balancer.

3. Description of device: The device consists of one unit, containing the force sensor and an electronic display. The eLIBRA® Soft-Tissue Force Sensor for a total knee replacement is a single use battery powered device designed to show relative forces on the integrated display. The eLIBRA® Unit is a non-reusable battery powered device designed to receive an electronic signal from the integrated force sensor. The unit displays a number from 0-20 for both the medial and lateral compartments in the knee joint to aid the surgeon in balancing soft tissue structures during a total knee arthroplasty (TKA).

4. Intended use: For use as a tool for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. The unit is sterile, for single patient use. (Unchanged from our predicate devices)

5. Technological characteristics: The technological characteristics are essentially identical to our predicate device with only one difference. The display was formerly reusable and wireless. The display is now integrated into the force sensor. The materials and construction techniques have not changed. The units are still battery operated. The sterilization and packaging techniques have not changed.

Predicate Device K070108	Modified Device
	
	Sensor integrated into display unit. See photo above.

6. Performance testing: Bench tests were performed. Bench testing included mechanical testing, force testing, electrical safety, EMC, and sterility testing, including EO residues. Software validation and risk analysis was conducted. The results were satisfactory and revealed no concerns over safety and effectiveness as compared to our predicate device. The tests demonstrated that the device is as safe, as effective, and performs in a substantially equivalent manner to the predicate device.

7. Conclusion: The indications for use has not changed from our predicate, and the technical changes involve only integrating the formerly wireless display into the force sensing unit. Therefore the modified device is as safe and effective as our predicate device and is substantially equivalent to that device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 21, 2014

Synvasive Technology Incorporated
% Mr. Danel Kamm, P.E.
Principal Engineer
8870 Ravello Court
Naples, Florida 34114

Re: K132104
Trade/Device Name: eLibra Soft Tissue Force Sensor
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: II
Product Code: ONN
Dated: September 4, 2013
Received: February 26, 2014

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132104

Device Name: eLibra Soft Tissue Force Sensor

Indications For Use:

For use as a tool for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. The force sensor is sterile, for single patient use.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices